## REMARKS

I. STATUS AND AMENDMENTS TO THE CLAIMS

In this Amendment, claims 1, 4, 5, 6, 8, 9, and 10 are amended, and claims 2, 3, 7, and 11 are canceled. Claim 12 is new.

Specifically, independent claim 1 has been amended to incorporate dependent claims 3 and 7, which are now canceled.

Independent claim 1 has further been amended to recite a step of "culturing malignant epithelial cells from a patient tumor, ascites fluid, or pelvic washing," as is supported for example by the original claims and by pages 5-6 of the specification.

Independent claim 1 has further been amended to clarify that the patient's cells have an unknown chemosensitivity profile, as is clearly described throughout the application (e.g., see BACKGROUND OF THE INVENTION).

Independent claim 1 has further been amended to recite that the level of caspase-3 activity induced by each agent is a positive predictor of a clinical response, as is also described throughout the application.

New claim 12 is supported by page 19 of the specification for example.

The remaining amendments are made for clarity and consistency with the independent claims.

No new matter has been introduced.

Entry of this Amendment is requested.

II. RESPONSE TO REJECTIONS UNDER 35 USC §102(b)

(1) At page 2 of the Office Action, claims 1-9 and 11 are rejected as being anticipated by Cuello et al., *Gynecol. Oncol.* 81(3):380-90 (2001).

(2) At page 3 of the Office Action, claims 1-11 are rejected as being anticipated by Ofir et al., *Cell Death and Differentiation* 9:636-642 (2002).

(3) At page 3 of the Office Action, claims 1-5, 7, 8, 10, and 11 are rejected as being anticipated by Kolfschoten et al., *Gynecologic Oncol.* 84:404-412 (2002).

Independent claim 1 has been amended to clarify that ***the invention involves predicting a clinical response for chemotherapeutic agents for a patient***, and thus aids the selection of an individualized chemotherapeutic regimen. See pages 1-3 of the specification.

While the references cited may disclose caspase-3 assays for detecting apoptosis, they do not disclose any correlation between caspase-3 activity detected *ex vivo* and a clinical response. To illustrate this point, the Examiner's attention is directed to the accompanying references:

(1) Kim et al., Induction of apoptosis in human leukemia cells by 3-deazaadenosine is mediated by caspase-3 like activity, *Experimental and Molecular Medicine* 32(4):197-203 (2000); and

(2) Staib et al., Determination of caspase-3 activation fails to predict chemosensitivity in primary acute myeloid leukemia blasts, *BMC Cancer* 5:60 (2005).

***Together these references show that, while caspase-3 activity can be detected as an in vitro marker of apoptosis in leukemia cells (a non-epithelial cancer), it fails as a surrogate marker for a clinical response.***

In the present application, none of the cited references disclose culturing patient cells having an unknown chemoresponse profile, contacting the cultured cells with a plurality of agents, and detecting the level of caspase-3 activity as a surrogate marker for a positive clinical response. Accordingly, none of the cited references teach or suggest the present invention.

In addition, with respect to Cuello, Cuello shows that cancer cell lines known to be resistant to chemotherapy may be synergistically affected by the addition of TRAIL *in vitro*.

In addition, with respect to Ofir and Kolfschoten, these references do not disclose contacting the cultured cells with a plurality of agents, such that the more effective agent may be selected for therapy.

Accordingly, the references do not disclose nor suggest the claimed invention.

Withdrawal of the rejections is respectfully requested.

## III. CONCLUSION

In view of the foregoing, Applicants respectfully submit that this application is in condition for allowance. However, the Examiner is requested to call the undersigned if any questions or comments arise.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

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Respectfully submitted,
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